



Billing Code 3410-DM-P

DEPARTMENT OF AGRICULTURE

Food Safety and Inspection Service

9 CFR Part 557

[Docket No. FSIS-2018-0030]

RIN 0583-AD73

**Eligibility of the People's Republic of China to Export
Siluriformes Fish and Fish Products to the United States**

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is amending the Siluriformes fish inspection regulations to list the People's Republic of China (PRC) as a country eligible to export Siluriformes fish and fish products to the United States. FSIS has reviewed the PRC's laws, regulations, and inspection system as implemented and has determined that the PRC's Siluriformes fish inspection system is equivalent to the system that the United States has established under the Federal Meat Inspection Act (FMIA) and its implementing regulations. Under this final rule, only raw Siluriformes fish and fish products produced in certified PRC establishments are eligible for export to the United States. All such products are subject to re-inspection at U.S. points-of-entry by FSIS inspectors.

DATES: *Effective Date:* [INSERT DATE 30 DAYS AFTER THE DATE OF PUBLICATION IN THE FEDERAL REGISTER].

FOR FURTHER INFORMATION CONTACT: Terri Nintemann, Assistant Administrator, Office of Policy and Program Development, Food Safety and Inspection Service, U.S. Department of Agriculture; Telephone: (202) 205-0495.

SUPPLEMENTARY INFORMATION:

Background

On September 19, 2018, FSIS proposed to amend its regulations at 9 CFR 557.2(b)(1) to add the PRC as a country eligible to export Siluriformes fish to the United States (83 FR 47524) (for convenience, in this final rule, "Siluriformes fish and fish products" will be shortened to "Siluriformes fish"). Although the PRC has been allowed to export these products to the United States under the conditions described in the proposed rule (83 FR 47524), the PRC is not currently listed in the Code of Federal Regulations (CFR) as eligible to export Siluriformes fish to the United States. FSIS proposed to add the PRC to the regulations as eligible to export such products after the Agency conducted a documentary review of the PRC's laws, regulations, and Siluriformes fish inspection system, as well as an in-country audit of the system, and determined that the PRC's Siluriformes fish inspection system is equivalent to the U.S. system established under the FMIA and its implementing

regulations. This final rule is consistent with the provisions of the proposed rule.

Statutory and Regulatory Basis for Final Action

As explained in the proposed rule (83 FR 47524), Siluriformes fish are an amenable species under the FMIA (21 U.S.C. 601(w)(2)). The FMIA prohibits importation into the United States of adulterated or misbranded meat and meat food products (21 U.S.C. 620). Under the FMIA and its implementing regulations, Siluriformes fish imported into the United States must be from foreign countries that maintain an inspection system that ensures compliance with requirements equivalent to the inspection, sanitary, quality, species verification, and residue standards in the United States, and all other provisions of the FMIA that are applied to official establishments in the United States. The regulatory requirements for foreign countries to become eligible to export Siluriformes fish to the United States are provided in 9 CFR 557.2, which cross-references 9 CFR 327.2, the regulations for the import of other products also subject to the FMIA.

Section 557.2(a) (cross-referencing 9 CFR 327.2 (a)(1), (a)(2)(i), (a)(2)(ii)(C)-(I), (a)(2)(iii)-(iv), and (a)(3)), requires a foreign country's inspection system be authorized by legal authority that imposes requirements equivalent to those of

the United States, specifically with respect to: (1) official controls by the national government over establishment construction, facilities, and equipment; (2) direct official supervision of the preparation of product to assure that product is not adulterated or misbranded; (3) separation of establishment operations for product certified for export from product that is not certified; (4) requirements for sanitation at certified establishments and for the sanitary handling of product; (5) official controls over condemned materials; (6) a Hazard Analysis Critical Control Point (HACCP) system; and (7) any other requirements found in the FMIA and its implementing regulations.

In addition to a foreign country's legal authority and regulatory requirements, the inspection program must achieve a level of public health protection equivalent to that achieved by the U.S. inspection program. Specifically, the inspection program organized and administered by the national government must impose requirements equivalent to those of the United States with respect to: (1) organizational structure and staffing, so as to ensure uniform enforcement of the requisite laws and regulations in all certified establishments; (2) ultimate control and supervision by the national government over the official activities of employees or licensees; (3) competent, qualified inspectors; (4) enforcement and

certification; (5) administrative and technical support; (6) inspection, sanitation, quality, species verification, and residue standards; and (7) any other inspection requirements required by the regulations in Subchapter F – Mandatory Inspection of Fish of the Order Siluriformes and Products of Such Fish, which cross-references 9 CFR 327.2(a)(2)(i).

Annually, the foreign country certifies the establishments as having met the required standards and notifies FSIS about establishments that are certified or removed from certification (9 CFR 557.2, cross-referencing 9 CFR 327.2(a)(3)).

Evaluation of the PRC Siluriformes Fish Inspection System

As discussed in the proposed rule (83 FR 47524), in March 2017, based on the PRC's request, FSIS conducted a document review of the PRC's Siluriformes fish inspection system to determine whether that system was equivalent to that of the United States. Based on its review of the submitted documentation, which included the PRC's laws, regulations, and inspection procedures, FSIS concluded that the PRC's inspection system is equivalent to those of the United States for raw Siluriformes fish products, specifically Siluriformes fish that fall within the FSIS product categories "Raw Product – Intact" and "Raw Product – Non-Intact." Both product categories are defined in the "FSIS Product Categorization" document, which was developed to assist foreign governments in accurately

identifying the type of meat and poultry products exported to the U.S. This document can be found on the FSIS website at: [https://www.fsis.usda.gov/shared/PDF/FSIS Product Categorization .pdf](https://www.fsis.usda.gov/shared/PDF/FSIS_Product_Categorization.pdf).

Accordingly, from May 28 to June 4, 2018, FSIS proceeded with an initial on-site audit of the PRC's Siluriformes fish inspection system. The purpose of the on-site audit was to verify whether the PRC's General Administration of Customs (GACC), the Central Competent Authority (CCA) for food inspection, effectively implemented a Siluriformes fish inspection system equivalent to that of the United States. The PRC currently exports only raw Siluriformes fish to the United States.

The audit did not identify any deficiencies that represented an immediate threat to public health, but did identify deficiencies that could lead to product contamination if not adequately addressed. In the audit exit meeting, GACC committed to address the findings as presented. For more detailed information on FSIS's evaluation of the PRC's Siluriformes fish inspection system see the proposed rule (83 FR 47524) and for the full audit report, go to:

<https://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/eligible-countries-products-foreign-establishments/foreign-audit-reports>.

From November 26 through December 13, 2018, FSIS performed a follow-up audit in response to the deficiencies identified in the initial on-site audit. During the initial audit, FSIS was only able to observe processing in two out of the six audited establishments. In the follow-up audit, the FSIS auditors visited seven out of ten establishments exporting products to the United States at that time. At the time of the follow-up audit, all seven establishments were processing Siluriformes fish. The FSIS auditors observed the production of Siluriformes fish, in addition to the implementation of corrective actions to the inspection system deficiencies noted during the initial on-site audit. FSIS did not identify any deficiencies that represented an immediate threat to public health and has determined that the proposed corrective actions are adequate. For the full audit report, go to:

<https://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/eligible-countries-products-foreign-establishments/foreign-audit-reports>.

Final Rule

After considering the comments received on the proposed rule, discussed below, FSIS concludes that the PRC's Siluriformes fish inspection system is equivalent to the United States inspection. Therefore, FSIS is amending its Siluriformes fish inspection regulations to list as the People's Republic of

China as a country eligible to export Siluriformes fish to the United States. As stated above, under FSIS's Siluriformes fish import regulations, the PRC must certify to FSIS that those establishments that wish to export Siluriformes fish to the United States are operating under requirements equivalent to those of the United States (9 CFR 557.2(a)).

Although a foreign country may be listed in FSIS regulations as eligible to export Siluriformes fish to the United States, the exporting country's products must also comply with all other applicable requirements of the United States. Accordingly, Siluriformes fish exported to the United States from the PRC will continue to be subject to re-inspection by FSIS at U.S. points-of-entry for, but not limited to, transportation damage, product and container defects, labeling, proper certification, general condition, and accurate count. In addition, FSIS will continue to conduct other types of re-inspection activities, such as taking product samples for laboratory analysis to detect drug and chemical residues and pathogens, as well as to identify product species and composition. Products that pass re-inspection will be stamped with the official mark of inspection and allowed to enter U.S. commerce. If they do not meet U.S. requirements, they will be refused entry and within 45 days must be exported to the country of origin, destroyed, or converted to animal food (subject to

approval of the U.S. Food and Drug Administration (FDA)), depending on the violation. FSIS import re-inspection activities can be found on the Agency's website at:
<http://www.fsis.usda.gov/wps/portal/fsis/topics/international-affairs/importing-products/port-of-entry-procedures>.

Responses to Comments

FSIS received 29 comments from individuals, Siluriformes fish and fish product producers from the PRC and the United States, trade associations, a commercial workers union, a frozen storage corporation, and a consumer interest group. The issues raised in the comments and the Agency responses are summarized below.

The Effectiveness of the PRC's Inspection System and Ongoing Verification of Compliance

Comment: Comments from six individual consumers, a U.S. Siluriformes fish and fish products producer, a labor group, two trade associations, and a consumer group questioned whether the PRC's Siluriformes fish inspection system was truly equivalent to that of the United States, and whether Siluriformes fish processed under that system would be safe for consumption in the United States. One of the two trade association that questioned whether the PRC's regulatory and inspections systems are

equivalent to that of the United States submitted peer-reviewed articles concerning the use of antibiotics in aquaculture.

Response: FSIS made its equivalence determination for the PRC's Siluriformes fish inspection system based on sound science and in accordance with U.S. international obligations and its own equivalence process. FSIS has an in-depth and rigorous equivalence process, through which it systematically determines whether a foreign country's inspection system achieves a level of public health protection equivalent to that achieved by the U.S. inspection system. Accordingly, the equivalence process does not require the exporting country to develop and implement the same procedures as those of the United States. Once a country is considered to have an equivalent food safety inspection system, the FSIS equivalence process includes performing an annual records review and on-going on-site audits of the country's inspection system at least every three years to verify whether the country's inspection system continues to be equivalent to FSIS's inspection system.

Regarding antibiotic residues as discussed above, FSIS performs an annual records review for each country that has been deemed to have an equivalent inspection system to that of the United States which includes, in part, a review of the country's sampling and testing for residues; in short, FSIS annually verifies the adequacy of each equivalent country's residue

testing program. In addition, FSIS conducts point-of-entry re-inspection of all imported Siluriformes fish, which can include product sampling and testing for microbial, chemical and other hazards. FSIS may conduct laboratory analysis for the detection of chemical residues that may result from the use of drugs and pesticides, or from incidents involving environmental contaminants. FSIS analyzes imported Siluriformes fish for over 100 chemical compounds, which include drugs, aminoglycosides, antifungal drugs, metals and pesticides. Products that pass re-inspection are stamped with the official mark of inspection and allowed to enter U.S. commerce. If they do not meet U.S. requirements, they are refused entry into U.S. commerce and must be re-exported, destroyed, or converted to animal food.

On-site Audit

Comment: The commercial workers union and the consumer interest group expressed concerns over the deficiencies found during the initial on-site audit and the number of PRC establishments audited.

Response: The results of the initial on-site audit, conducted from May 28 through June 4, 2018, were shared with the PRC's CCA. The CCA provided corrective actions to address the deficiencies that were deemed adequate by FSIS.

On November 26 through December 13, 2018, FSIS performed a follow-up audit of the PRC's food safety system governing fish

and fish products of the order Siluriformes, in response to the deficiencies identified during the initial on-site audit (May 28 through June 4, 2018). During the initial audit, FSIS was only able to observe processing of Siluriformes fish in two out of the six audited establishments. In the follow-up audit, the FSIS auditors visited seven out of the ten establishments that then exported products to the United States. At the time of this audit, all seven establishments were processing Siluriformes fish. The FSIS auditors observed the processing of Siluriformes fish products, in addition to the implementation of corrective actions to the inspection system deficiencies noted during the initial on-site audit. FSIS did not identify any deficiencies that represented an immediate threat to public health and determined that the proposed corrective actions were adequate.

It is important to note that FSIS equivalence determinations are based on the foreign country's inspection system, not on an individual establishment's system. To be eligible to export Siluriformes fish to the United States, the foreign country's inspection system must ensure that establishments preparing these products for export to the United States comply with requirements equivalent to those of the FMIA and supporting regulations. The PRC's inspection system meets these requirements. The foreign country certifies the establishments as meeting the required standards and notifies

FSIS about establishments that are certified or removed from certification. The PRC's inspection system currently meets all these requirements. FSIS will verify that the system continues to meet requirements through annual CCA submissions, on-going audits, and point-of-entry re-inspection and sampling and testing.

Executive Orders (E.O.s) 12866 and 13563

E.O. 12866 and 13563 direct agencies to assess all costs and benefits of available regulatory alternatives and, if regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety effects, distributive impacts, and equity). E.O. 13563 emphasizes the importance of quantifying both costs and benefits, of reducing costs, of harmonizing rules, and of promoting flexibility. This final rule has been designated a "non-significant" regulatory action under section 3(f) of E.O. 12866. Accordingly, the rule has not been reviewed by the Office of Management and Budget under E.O. 12866.

Expected Costs of the Final Rule:

This final regulatory impact analysis updates the preliminary regulatory impact analysis by including the most recent year's (2018) trade data. As shown in Table 1, in 2018, the PRC accounted for approximately 5.9 percent of Siluriformes

fish imports and represented only 3.6 percent of Siluriformes fish consumption in the United States. The final rule is not expected to change the PRC's market share or to impose any cost on industry or consumers, because the final rule will maintain historical trade.

Table 1. Summary of Siluriformes Sales*						
	2014	2015	2016	2017	2018	5 Year Average
	Millions of Dollars					
Total U.S. Imports¹	\$346.66	\$351.13	\$405.61	\$381.89	547.10	406.48
Total U.S. Domestic Production²	\$351.94	\$363.61	\$385.99	\$379.71	360.40	368.33
Total U.S. Exports¹	\$4.00	\$4.95	\$4.80	\$6.18	3.89	4.76
Total U.S. Consumption³	\$694.60	\$709.79	\$786.80	\$755.43	\$903.61	\$770.04
Total U.S. Imports from the PRC¹	\$36.19	\$32.06	\$37.46	\$38.35	\$32.20	\$35.25
The PRC as % of U.S. Imports	10.4%	9.1%	9.2%	10.0%	5.9%	8.7%
The PRC as % of U.S. Domestic Production	10.3%	8.8%	9.7%	10.1%	8.9%	9.6%
The PRC as % of U.S. Consumption	5.2%	4.5%	4.8%	5.1%	3.6%	4.6%
Data Source: U.S. Census Bureau Trade Data * Numbers in table may not sum to totals due to rounding ¹ Import and Export Data Accessed from USDA Foreign Agricultural Service: Global Agricultural Trade System: https://apps.fas.usda.gov/gats/default.aspx/ ² U.S. Production Data Accessed from USDA National Agricultural Statistics Service: Quick Stats: https://quickstats.nass.usda.gov/results/6F6BAB14-7014-365B-ACEA-CA35C184329B?pivot=short_desc ³ U.S. Consumption data is assumed to equal Imports + Domestic Production - Exports						

Expected Benefits of the Final Rule:

This final rule will maintain the Siluriformes fish trade between the United States and the PRC and its associated benefits. As shown in Table 2, the United States is the PRC's largest foreign customer of Siluriformes fish, purchasing on

average 60 percent of their total frozen catfish and frozen catfish fillets exports from 2016 to 2018. As shown in Table 1, the U.S. consumes more Siluriformes fish than it produces. U.S. production meets approximately half of U.S. total demand. Maintaining current trade flows will help keep consumer prices for Siluriformes fish affordable and meet the large U.S. demand for these products. Additionally, the PRC provides several species of Siluriformes fish that are not produced domestically, allowing for greater product diversity and consumer choice.

Table 2. Chinese Siluriformes Export Market Share by Country						
	USD in millions			% Share		
Partner Country	2016	2017	2018	2016	2017	2018
World	\$50.43	\$41.34	\$28.74	100%	100%	100%
United States	\$35.92	\$27.32	\$11.98	71%	66%	42%
Data Source: Global Trade Atlas - International Import and Export Commodity Trade Data (Numbers reported by Chinese Customs) Commodity: 030324- Catfish, Frozen and 030462- Catfish Fillets, Frozen FSIS downloaded the data from https://www.gtis.com , and it will be available upon request.						

Regulatory Flexibility Act Assessment

The FSIS Administrator certifies that, for the purposes of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), this final rule will not have a significant economic impact on a substantial number of small entities in the United States, because, as stated above, the final rule will maintain existing

trade. The trade volume is expected to remain within historical bounds, with little or no effect on U.S. establishments, regardless of size.

Executive Order (E.O.) 13771

Consistent with E.O. 13771 (82 FR 9339, February 3, 2017), this final rule facilitates regulatory cooperation with foreign governments. Therefore, this final rule is an E.O. 13771 deregulatory action.

Paperwork Reduction Act

No new paperwork requirements are associated with this final rule. Foreign countries wanting to export Siluriformes fish to the United States are required to provide information to FSIS certifying that their inspection system provides standards equivalent to those of the United States, and that the legal authority for the system and the implementing regulations are equivalent to those of the United States. FSIS provided the PRC with a questionnaire, referred to as the Self Reporting Tool (SRT), asking for detailed information about the country's inspection practices and procedures to assist the country in organizing its materials. This information collection was approved under OMB number 0583-0153. The rule contains no other paperwork requirements.

Executive Order (E.O.) 12988, Civil Justice Reform

This final rule has been reviewed under E.O. 12988, Civil Justice Reform. Under this rule: (1) All State and local laws and regulations that are inconsistent with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) no administrative proceedings will be required before parties may file suit in court challenging this rule.

E-Government Act

FSIS and USDA are committed to achieving the purpose of the E-Government Act (44 U.S.C. 3601, et seq.) by, among other things, promoting the use of the internet and other information technologies and providing increased opportunities for citizens access to Government information and services, and for other purposes.

Additional Public Notification

Public awareness of all segments of rulemaking and policy development is important. Consequently, FSIS will announce this **Federal Register** publication online through the FSIS web page located at: <http://www.fsis.usda.gov/federal-register>.

FSIS will also announce and provide a link to it through the FSIS *Constituent Update*, which is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, and other types of information that could affect or would be of interest to our constituents and stakeholders. The *Constituent Update* is

available on the FSIS web page. Through the web page, FSIS is able to provide information to a much broader, more diverse audience. In addition, FSIS offers an e-mail subscription service which provides automatic and customized access to selected food safety news and information. This service is available at: <http://www.fsis.usda.gov/subscribe>. Options range from recalls to export information, regulations, directives, and notices. Customers can add or delete subscriptions themselves, and have the option to password protect their accounts.

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Washington, DC 20250-9410

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E-mail: program.intake@usda.gov

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List of Subjects in 9 CFR Part 557

Imported products.

For the reasons set out in the preamble, FSIS amends 9 CFR part 557 as follows:

PART 557—IMPORTATION

1. The authority citation for part 557 continues to read as follows:

Authority: 21 U.S.C. 601-602, 606-622, 624-695; 7 CFR 2.7, 2.18, 2.53.

2. In § 557.2, revise paragraph (b) (1) to read as follows:

§ 557.2 Eligibility of foreign countries for importation of fish and fish products into the United States.

* * * * *

(b) (1) It has been determined that fish and fish products from the following countries covered by foreign inspection certificates of the country of origin as required by §557.4, are eligible under the regulations in this subchapter for entry into the United States after inspection and marking as required by the applicable provisions of this part: People's Republic of China.

* * * * *

Done at Washington, DC:

Carmen M. Rottenberg,

Administrator.

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